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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,940	01/02/2001	Rainer Oschmann	113.1009	8398

7590 06/21/2005

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/720,940	Applicant(s) OSCHMANN ET AL.	
	Examiner Sabiha Qazi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 11-18 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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Final Office Action

Claims 11-18 are pending. Amendments are entered. Acknowledgment is made of the response filed on 3/7/05.

Response to Remarks

The Applicants have claimed a product-by-process. The MPEP, in section 2113, states: "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is *unpatentable even though the prior product was made by a different process.*"

The Examiner believes that the process of ultrafiltration will produce a product that is obvious over the prior art. The claim is unpatentable, even though a different process made the prior product.

Double Patenting – First Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-18 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,328,999. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference generically teaches the instant invention.

The reference teaches an extract from ginkgo biloba leaves comprising: 20 to 30% by weight flavonol glycosides a total of 2.5 to 4.5% by weight of ginkgolides A, B, C and J 2.0 to 4.0% by weight bilobalide below 10 ppm alkyl phenol compounds below 10% by weight proanthocyanidins below 50 ppm 4'-O-methylpyridoxine below 100 ppm biflavones, which generically teaches the instant invention.

Even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

The Applicants have claimed a product-by-process. The MPEP, in section 2113, states: "If the product in the product-by-process claim is the same as or obvious from a product of the

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prior art, the claim is *unpatentable even though the prior product was made by a different process.*"

The Examiner believes that the process of ultrafiltration will produce a product that is obvious over the prior art. The claim is unpatentable, even though a different process made the prior product.

Double Patenting – Second Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 11-18 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,512,286. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference generically teaches the instant invention.

The reference teaches an extract from the leaves of Ginkgo biloba containing most of the flavone glycosides, ginkgolides and bilobalide originally present in the leaves, comprising 20 to 30 weight percent flavone glycosides, 2.5 to 4.5 weight percent ginkgolides selected from the group consisting of ginkgolide A, B, C and J and mixtures thereof, 2.0 to 4.0 weight percent bilobalide and less than 10 ppm alkylphenol compounds, said extract being essentially free of components of the leaves with serum-precipitating or hemagglutinating properties, which generically teaches in the instant invention.

Even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

The Applicants have claimed a product-by-process. The MPEP, in section 2113, states: "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is **unpatentable** even though the prior product was made by a different process."

The Examiner believes that the process of ultrafiltration will produce a product that is obvious over the prior art. The claim is unpatentable, even though a different process made the prior product.

Double Patenting – Third Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-18 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,399,099. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference generically teaches the instant invention.

An effervescent composition for oral administration comprising a dry extract of ginkgo biloba comprising from 20-30% by weight of flavone glycosides and from about 4.5-8.5% by weight of terpenoids, which generically teaches the instant invention.

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Even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

The Applicants have claimed a product-by-process. The MPEP, in section 2113, states: "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is **unpatentable** even though the prior product was made by a different process."

The Examiner believes that the process of ultrafiltration will produce a product that is obvious over the prior art. The claim is unpatentable, even though a different process made the prior product.

Double Patenting – Fourth Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-18 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,399,348. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference generically teaches the instant invention.

The reference teaches an extract comprising 20 to 30 weight percent flavone glycosides, 2.5 to 4.5 weight percent of ginkgolides A, B, C and J, 2.0 to 4.0 weight percent bilobalide, less than 10 ppm alkylphenol compounds and less than 10 weight percent proanthocyanidins, which generically teaches the instant invention.

Even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

The Applicants have claimed a product-by-process. The MPEP, in section 2113, states: "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is *unpatentable even though the prior product was made by a different process.*"

The Examiner believes that the process of ultrafiltration will produce a product that is obvious over the prior art. The claim is unpatentable, even though a different process made the prior product.

Double Patenting – Fifth Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-18 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 of U.S. Patent No. 5,322,688. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference generically teaches the instant invention.

The reference teaches an extract from the leaves of Ginkgo biloba, which is substantially free of alkylphenol compounds, and having a high content of flavone glycosides and comprising

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substantially all of the ginkgolides and bilobalide originally present in the leaves, which generically teaches the instant invention.

Even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

The Applicants have claimed a product-by-process. The MPEP, in section 2113, states: "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is *unpatentable even though the prior product was made by a different process.*"

The Examiner believes that the process of ultrafiltration will produce a product that is obvious over the prior art. The claim is unpatentable, even though a different process made the prior product.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 rejected under 35 U.S.C. 102(b) as anticipated by:

1. Japanese Unexamined Patent Publication (A) No. 279300/1994 (Translation). Publication Date: 10/4/1994, The reference disclose a water-soluble Ginkgo leaf extract containing at least 20% flavone glycoside and atleast 5.6% terpene lactones. See abstract, claims pages 3-11Table 1, and page 20-21.

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2. Liu, Zheng et al. (AN 1997:82596, HCAPLUS, abstract of Huaxue Shijie (1996), 37(7), 355-358). The references disclose a water-soluble extract containing total flavones from *Ginkgo biloba* leaves.

The cited references disclose presently claimed invention.

Applicant must note a technical difference, that claims are drawn to a product "water soluble extract of *Ginkgo biloba*" and not on the process of making or method of producing such as extract. Water-soluble products are known marketed products see prior art of record).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over:

1. Japanese Unexamined Patent Publication (A) No. 279300/1994 (Translation). Publication Date: 10/4/1994, The reference disclose a water-soluble Ginkgo leaf extract containing at least 20% flavone glycoside and atleast 5.6% terpene lactones. See abstract, claims pages 3-11 Table 1, and page 20-21.
2. Liu, Zheng et al. (AN 1997:82596, HCAPLUS, abstract of Huaxue Shijie (1996), 37(7), 355-358). The references disclose a water-soluble extract containing total flavones from *Ginkgo biloba* leaves.

Instant claims differ from the reference in claiming an extract obtained by "ultrafiltration". The Applicants have claimed a product-by-process. The MPEP, in section 2113, states: "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is *unpatentable even though the prior product was made by a different process.*" The Examiner believes that the process of ultrafiltration will produce a product that is obvious over the prior art. The claim is unpatentable, even though a different process made the prior product.

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It would have been obvious to one skilled in the art to prepare a dry extract as presently claimed, even if the prior art does not use the word "ultrafiltration", the claims have been subjected to other separation techniques, bringing the extract to similar ingredients/constituents as has been taught by the prior art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

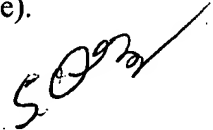
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER

Sunday, June 12, 2005